REVISED per FDA request May 12, 2004

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Food Contact Notification for a Food Contact Substance:
A multilayer, transparent, flexible polymer film
for holding beverages
FCN # 415

Tetra Pak Inc., c/o Eric F. Greenberg, Eric F. Greenberg, PC
3500 Three First National Plaza, Chicago, Illinois 60602

Environmental Assessment

I. Date: May 12, 2004

II. Name of Sponsor: Tetra Pak Inc.

III. Address: 101 Corporate Woods Parkway
Vernon Hills, IL 60061
c/o Eric F. Greenberg
Eric F. Greenberg, PC
3500 Three First National Plaza
Chicago, IL 60602-4283

IV. Description of the proposed action

A. Requested Approval

To obtain food additive clearance through food contact notification regarding the food contact substance containers for juice, juice drinks and other non-carbonated beverages stored and consumed at room temperature and below.

B. Need for Action

is an aseptic, flexible, stand-up-pouch for juice, juice drinks and other non-carbonated beverages at room temperature and below, that require packaging with a good oxygen barrier. The package is accompanied by an attached straw. The intended technical effect of is to provide effective holding, protection and distribution of beverages in a lightweight package that allows consumers to see the package contents. The structure is designed to limit the diffusion of oxygen, water vapor and aromas, and therefore provide the necessary barrier properties to maintain nutrition, safety and flavor of beverages without refrigeration. End use conditions will be room temperature and below, and this FCN seeks clearance for use of the FCS at conditions E, F, and G in 21

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CFR Section 176.170(c), Table 2. Foods, specifically beverages, to be packaged in the FCS will be aqueous or acidic, and dairy (oil in water emulsions) corresponding with categories I, II, IVB and VIB in 21 CFR Section 176.170(c), Table 1.

C. Location of Use

The subject packaging material structure will be manufactured from polymer resin and film components at Tetra Pak converting plants. Beverage processing and package filling will take place on Tetra Pak filling equipment at independent co-packing facilities and at the manufacturing plants of Tetra Pak's customers, beverage and food companies who market and produce branded and private label beverages and foods throughout the USA.

Food packaging materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the country.

D. Locations of Disposal

The structure is expected to be used in production plants located throughout the United States. Food-packaging materials are expected to be used by consumers in patterns corresponding to national population density with disposal widely distributed across the country. These materials will ultimately be deposited in municipal solid waste landfills or combusted.

V. Identification of substances that are the subject of the proposed action

The food contact substance which is the subject of the proposed action is VTMOS-grafted LDPE, trade name Orevac 18112 supplied by Atofina, blended with LDPE.

CAS Name for VTMOS: Ethenyltrimethoxysilane
CAS # 2768-02-7
Trade or common name: vinyltrimethoxysilane; Orevac 18112 (LDPE grafted with VTMOS) (supplied by Atofina)
MF is $C_5H_{12}O_3Si$
MW: 148.23

VI. Environmental consequences of the proposed action

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A. Environmental Consequences of Manufacturing

No extraordinary circumstances pertain to the manufacture of this food contact substance, in that, for example, there are no unique emission circumstances that are not adequately addressed by general or specific emission requirements. This includes occupational

protections promulgated by Federal, State or local environmental agencies such that such emissions may harm the environment, the proposed action does not threaten to violate Federal, State or local environmental laws or requirements, and production of the food contact substance is not expected to adversely affect a species or the critical habitat of an endangered or threatened species, or of wild fauna or flora protected under some other Federal law.

B. Environmental Consequences of Use

Little or no introduction of any component of the VTMOS-modified LDPE/LDPE blend into the environment will result from its use in manufacturing the food-packaging materials or from its use in packaging food because this substance is almost completely incorporated into food-packaging materials and essentially all of it is expected to remain with this packaging throughout use of this product.

As discussed under Format Item IV. D above, only very small quantities of substances, if any, will be introduced into the environment as a result of use/disposal of the food contact substance. Consequently, no information needs to be provided on the fate of substances released into the environment as a result of such use and disposal.

C. Environmental Consequences of Disposal

No information needs to be provided on environmental effects of substances released into the environment as a result of such use and disposal of , because only small quantities, if any, of substances will be introduced into the environment as a result of use and disposal of this product. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, including the Clean Air Act, 42 U.S.C. §7401, *et seq.* and the Clean Water Act, 33 U.S.C. §1251 *et seq.*

1. Market Volume

The intended uses of the packaging material include beverage stand-up-pouches for juice, juice drinks, flavored waters, sports drinks, energy drinks, flavored milks and other still or non-carbonated beverages. According to figures from the Beverage Marketing Corporation, in 2002, beverages overall were packaged 47.0% in cans (99,013.1 million units), 25.3% in plastic bottles (53,233.4 million units), 17.4% in glass (36,525.1 million units), 7.7% in paper (16,124.8 million units), 1.2% in aseptic cartons (2,557.0 million units), and 1.4% in pouches (3,050.0 million units). The majority of the 5,607 million total aseptic cartons and pouches in the USA beverage market in 2002 were in shelf stable, single serve sizes of juices, nectars, juice drinks, and sports drinks. *Source: Beverage Marketing Corporation*

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2. Types of food contact articles and food applications

Tetra Pak expects that its packages will replace some foil and plastic stand-up-pouches, some aseptic carton, and some small-size PET bottles. Tetra Pak's projected 5-year market share information can be found in Confidential Attachment #1.

3. Disposal Patterns

According to EPA's report on municipal solid waste ("MSW"), approximately 57% of all MSW is landfilled, 16% is combusted, and 27% is recovered for composting or recycling. See *Characterization of Municipal Solid Waste in the United States: 1996 Update,* EPA530-R-97-015, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1997.

Flexible, stand-up-pouches for juice, juice drinks and other non-carbonated beverages are not recycled because they are so source reduced as to render recycling economically challenging.

D. Assessing Potential Impacts Resulting From Disposal

1. Source Reduction

The USEPA establishes source reduction as the most important tool to minimize the solid waste handling impacts of packaging. It is preferred even over recycling. That is, recycling is important to conserve resources and reduce the strain on landfills. Source reduction accomplishes both of these purposes and in addition minimizes or eliminates the economic and environmental costs of recycling – i.e. the costs of pick-up, transport and separation of recyclables. The structure represents a significant source reduction over competing pouch beverage packaging. Pouches, of course, represent a significant reduction in volume of material utilized over solid structures of polymer or glass.

The solid waste benefit of source reduction can be seen in the following table. The weight of 100 of each package type needed to deliver 20,000 ml of beverage is listed in the second column. Assuming that the leading pouch and were not recycled, but 50% of the other packages were recycled, the amount of material (in grams) going to the landfill can be seen in the third column:

Package type	**weight**	**material going to landfill**
		[1]
Leading pouch	47	47 – no recycling

[1] See Confidential Attachment # 1 for data on

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HDPE bottle	16,400	8,200 - 50% recycling
PET bottle	23,500	11,750 – 50% recycling
Glass bottle	89,700	44,850 – 50% recycling

2. Energy

It is unlikely that there will be any adverse effects on energy. In fact, there will be some benefits. For example,] will use less energy in transport because it weighs less than its competitive packages. That is, trucks delivering beverages generally "fill up" when their weight reaches the maximum allowable weight – rather than when the volume of the truck fills up. Since ' veighs less, the shipper can transport more filled TWA Clear packages to their destination.

VII. Mitigation Measures

As noted elsewhere in this assessment, no significantly adverse environmental effects of use of disposal of the subject material have been identified. Therefore, no mitigation measures will be necessary.

VIII. Alternatives to the proposed action

As noted elsewhere in this assessment, no significantly adverse environmental effects of use of disposal of the subject material have been identified. Therefore, no mitigation measures will be necessary.

IX. List of Preparers

Eric F. Greenberg, Attorney at Law, Eric F. Greenberg, P.C., Chicago, Illinois, He has over 20 years of experience in Food and Drug Law, including food additive and packaging issues.

Edward A. Klein, VP, Public and Environmental Affairs for Tetra Pak. He was a Division Director in the Office of Toxic Substances in the USEPA and also directed its Solid Waste Agenda for action in 1988.

Denise Miley, Manager, R&D North America, Tetra Pak Research & Development AB. BS Chemical Engineering, University of Wisconsin – Madison, 1984; MS Polymer Science, Pennsylvania State University, 1989; MM Northwestern University, 1995. She has 12 years of combined experience in the chemical, food and packaging industries.

X. References

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XI. Attachments

Confidential Attachment 1

Signature:

Tetra Pak Inc.

By: _____

Eric F. Greenberg
Its Attorney

Eric F. Greenberg
Eric F. Greenberg, PC
3500 Three First National Plaza
Chicago, IL 60602-4283
(312) 977-4647
FAX (312) 977-4405
efgreenberg@uhlaw.com

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